12-27-99

A

Please type a plus sign (+) inside this box [+]

PTO/SB/05 (12/97)
Approved for use through 09/30/00. OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

jc713 U.S. PTO 12/22/99

UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b)

Attorney Docket No. 003764.P006 Total Pages 3

First Named Inventor or Application Identifier Jeong S. Lee

Express Mail Label No. EL370843196US

jc530 U.S. PTO 09/470009 12/22/99

ADDRESS TO: **Assistant Commissioner for Patents**
Box Patent Application
Washington, D. C. 20231

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. XX Fee Transmittal Form
(Submit an original, and a duplicate for fee processing)

2. XX Specification (Total Pages 13)
(preferred arrangement set forth below)
- Descriptive Title of the Invention
- Cross References to Related Applications
- Statement Regarding Fed sponsored R & D
- Reference to Microfiche Appendix
- Background of the Invention
- Brief Summary of the Invention
- Brief Description of the Drawings (if filed)
- Detailed Description
- Claims
- Abstract of the Disclosure

3. X Drawings(s) (35 USC 113) (Total Sheets 2)

4. ____ Oath or Declaration (Total Pages ___)
   a. ___ Newly Executed (Original or Copy)
   b. ___ Copy from a Prior Application (37 CFR 1.63(d))
   (for Continuation/Divisional with Box 17 completed) **(Note Box 5 below)**
   i. ___ DELETIONS OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).

5. ____ Incorporation By Reference (useable if Box 4b is checked)
The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

6. ____ Microfiche Computer Program (Appendix)

7. _____ Nucleotide and/or Amino Acid Sequence Submission
(if applicable, all necessary)
a. ____ Computer Readable Copy
b. ____ Paper Copy (identical to computer copy)
c. ____ Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

8. _____ Assignment Papers (cover sheet & documents(s))
9. _____ a. 37 CFR 3.73(b) Statement (where there is an assignee)
_____ b. Power of Attorney
10. _____ English Translation Document (if applicable)
11. _____ a. Information Disclosure Statement (IDS)/PTO-1449
_____ b. Copies of IDS Citations
12. _____ Preliminary Amendment
13. __X__ Return Receipt Postcard (MPEP 503) (Should be specifically itemized)
14. _____ a. Small Entity Statement(s)
b. Statement filed in prior application, Status still proper and desired
15. _____ Certified Copy of Priority Document(s) (if foreign priority is claimed)
16. __X__ Other: Express Mail Certification
Unsigned Declaration and Power of Attorney (5 pages)

17. **If a CONTINUING APPLICATION,** check appropriate box and supply the requisite information:
___ Continuation ____ Divisional ____ Continuation-in-part (CIP)
of prior application No: _

18. **Correspondence Address**
_____ Customer Number or Bar Code Label _____
(Insert Customer No. or Attach Bar Code Label here)
or
__X__ Correspondence Address Below

NAME Andrew C. Chen
BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP
ADDRESS 12400 Wilshire Boulevard
Seventh Floor
CITY Los Angeles STATE California ZIP CODE 90025-1026
Country U.S.A. TELEPHONE (408) 720-8598 FAX (408) 720-9397

UNITED STATES PATENT APPLICATION

for

NON-METAL REINFORCING MANDREL

Inventors:

Jeong S. Lee
Ken Wantink

prepared by:

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN
12400 Wilshire Boulevard
Seventh Floor
Los Angeles, California 90025-1026

Docket No.: 003764.P006

EXPRESS MAIL CERTIFICATE OF MAILING

"Express Mail" mailing label number EL370843196US Date of Deposit 12-22-99

I hereby certify that I am causing this paper or fee to be deposited with the United States Postal Service "Express Mail Post Office to Addressee" service on the date indicated above and that this paper or fee has been addressed to the Assistant Commissioner for Patents, Washington, D. C. 20231

Barbara Herz
(Typed or printed name of person mailing paper or fee)

(Signature of person mailing paper or fee)

NON-METAL REINFORCING MANDREL

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates generally to catheters. More particularly, the present invention relates to a non-metal reinforcing mandrel for use with such catheters.

Description of Related Art

In percutaneous transluminal coronary angioplasty (PTCA), catheters are inserted into the cardiovascular system via the femoral artery under local anesthesia. A pre-shaped guiding catheter is positioned in the coronary artery, and a dilatation catheter having a distensible balloon portion is advanced through the guiding catheter into the branches of the coronary artery until the balloon portion traverses or crosses a stenotic lesion. The balloon portion is then inflated with a fluid to compress the atherosclerosis in a direction generally perpendicular to the wall of the artery, thereby dilating the lumen of the artery. After the last dilation, the balloon is deflated so that the dilatation catheter can be removed from the dilated stenosis and blood flow can resume through the dilated artery.

Ongoing development work of the dilatation catheters has reduced the transverse dimensions of the catheters for angioplasty procedures both as to their outer diameters as well as to the wall thickness of the catheter's tubular components. This reduction has led to difficulties in designing dilatation catheters having small transverse dimensions while still maintaining adequate pushability for advancement of the dilatation catheter through the guiding catheter into the patient's coronary artery and across tight stenoses. The marginal or inadequate pushability has been particularly noticeable with over-the-wire catheters that have been adapted for use with guidewires having diameters not more than about 0.014 inch (0.356 mm).

One solution to this dilemma has been the use of a reinforcing mandrel 24, such as the one shown in Figures 1A and 1B. The catheter 10 typically has an inner tubular member 12 with an inner lumen 14 adapted to receive a guidewire with a maximum OD of less than about 0.014 inch. An outer tubular member 16 is generally disposed about the inner tubular member 12 such that the inner tubular member 12 extends through the outer tubular member 16 and an outer lumen 18 is defined therebetween. The inflatable member (e.g., a balloon) 20 has a proximal end 21 which is secured to the distal end of the outer tubular member 16 and a distal end 23 secured to the distal end of the inner tubular member 12 so as to seal off the outer lumen 18 and the interior of the inflatable member 20.

The reinforcing mandrel 24 is within the outer lumen 18 between the inner 12 and outer 16 tubular members and extends from the proximal end of the catheter 10 into the distal portion of the catheter 10 but typically ends short of the inflatable member 20. The mandrel 24 is usually a cylindrical, often tapered axle inserted onto a device such as a catheter 10 to provide support along the length of the given device. The mandrel 24 is typically secured at the proximal end of the mandrel 24 within the adapter (not shown) mounted at the proximal end of the catheter 10.

Although difficult to achieve during processing, it is often desirable to vary the diameter of the mandrel 24 to establish a predetermined amount of flexibility. For example, since it is generally desirable for the proximal section of the catheter 10 to be more stiff to assist in the catheter's pushability, the proximal section of the mandrel 24 is designed/fabricated to have a larger diameter than the diameter of the mandrel 24 in a more distal section of the catheter 10. The smaller diameter portion of the mandrel 24 extending into the distal section of the catheter shaft 10 preferably has a transverse dimension of at least 20% less than the transverse dimension of the proximal section of the mandrel 24. This variation in the diameter of the mandrel 24 provides flexibility in

the distal portion of the catheter 10 and allows the catheter 10 to track over the guidewire while still maintaining excellent pushability.

The mandrel 24 of the prior art is fabricated from a metal or metal alloy (hereinafter metal) rod. The metal mandrels 24 known in the prior art, however, have several inherent limitations. First, metal rods are generally too stiff for angioplasty procedures, and a too stiff rod reduces a catheter's trackability over a guidewire or other medical device. Not only is the rod often too stiff, but a metal rod is also more difficult to process. For example, the metal rod must be ground to the desired diameter for the various (i.e., proximal and/or distal) section and often still retains sharp edges along it's length that can damage the interior of the catheter shaft. Further, the dimensions of a metal mandrel are fixed during fabrication.

It would be advantageous to replace the metal mandrels of the prior art with a non-metal mandrel that has more easily varied dimensions and stiffness characteristics along the length of the mandrel. The ability to easily vary the dimensions and stiffness characteristics of a mandrel will also allow more freedom in the choice of materials for the catheter shaft itself. In other words, because the stiffness of the mandrel can be easily varied during processing, the proximal section of the mandrel can be made stiff enough to provide the desired pushability for the catheter. A mandrel having a stiff proximal section reduces the need for a stiff proximal section of the catheter shaft itself. Thus, the material for the proximal shaft of the catheter will no longer be limited to a stiff polymer. By allowing the use of a less stiff polymer in the proximal section, the non-metal mandrel will also substantially reduce the likelihood of kinking. In this manner, a mandrel having a stiffer proximal section will provide the desired pushability without having to sacrifice the flexibility of the distal shaft of the catheter.

SUMMARY OF THE INVENTION

An apparatus for providing support along the length of a catheter is described. The present invention consists of a mandrel fabricated from a non-metal. The mandrel may extend through the outer lumen of a dilatation catheter to provide added support and stiffness to the catheter shaft. The stiffness along the length of the non-metal mandrel may easily be varied by making dimensional or morphological changes to the polymeric mandrel.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is further described by way example with reference to the accompanying drawings, wherein:

Figure 1A is a side cross-sectional view of a mandrel of a first embodiment of the present invention as used with a dilation catheter.

Figure 1B is a front cross-sectional view of the mandrel and catheter illustrated in Figure 1A.

DETAILED DESCRIPTION OF THE INVENTION

An apparatus for providing support for a catheter is described. In the following detailed description, numerous specific details are set forth in order to provide a more thorough understanding of the present invention. However, it will be appreciated that the present invention may be practiced without these specific details. In other instances, well-known devices, methods, procedures, materials, and individual components have not been described in detail so as not to unnecessarily obscure aspects of the present invention.

A mandrel is usually a cylindrical, often tapered, axle/rod inserted into a device such as a catheter to provide support along the length of the device. In the prior art, mandrels used with biomedical devices have been fabricated from a metal or metal alloy (hereinafter metal). The metal mandrels, however, have been encumbered by several limitations including difficulty in processing mandrels having a desired varying diameter, sharp edges that may damage the device the mandrel is inserted into, and an often excessive stiffness. The present invention addresses each of the above issues by providing a non-metal mandrel.

Figures 1A and 1B are illustrations of a reinforcing mandrel 24 a used with a dilatation catheter 10. The catheter 10 has an inner tubular member 12 with an inner lumen 14 adapted to receive a guidewire (not shown). An outer tubular member 16 is generally disposed about the inner tubular member 12 such that the inner tubular member 12 extends through the outer tubular member 16 and an outer lumen 18 is defined therebetween. The inflatable member (e.g., a balloon) 20 has a proximal end 21 that is secured to the distal end of the outer tubular member 16, and a distal end 23

that is secured to the distal end of the inner tubular member 12 so as to seal off the outer lumen 18 and the interior of the inflatable member 20.

The reinforcing mandrel 24 is typically within the outer lumen 18 between the inner 12 and the outer 16 tubular members and extends from the proximal end of the catheter 10 into the distal portion/section of the catheter 10. The mandrel 24 typically ends short of the inflatable member 20.

The mandrel of the present invention is fabricated from a non-metal material. The material for the non-metal mandrel may be selected from numerous materials including, but not limited to: nylons, including high stiffness polyamides; stiff polymers with tensile modules greater than approximately 400,000 psi, such as PEEK (polyether etherketone), PPS (polyphenylene sulfide), PEI (polyetheramide), and PI (polyimide); liquid crystalline polymers; polymers reinforced with glass fibers; polymers reinforced with graphite fibers, etc.

By fabricating the mandrel of a catheter from a non-metal material, the present invention provides numerous advantages over the prior art. Without the use of a mandrel, the proximal section of a catheter shaft must generally be made of a stiff polymer in order to provide a sufficient amount of pushability. However, a stiff polymer shaft kinks easily during manipulation of the catheter into the desired position with the cardiovascular system of the patient. The metal mandrel of the prior art provides stiffness for the catheter in addition to the catheter shaft itself. However, the flexibility of a metal mandrel is difficult to vary, often resulting in a too stiff mandrel which makes the steering of the catheter much more difficult. The stiffness of the non-metal mandrel of the present invention may be varied as needed along the length of the mandrel as

requested by the desired stiffness characteristics of a given section of the mandrel. For example, it is generally desirable for the proximal section of the catheter to be more stiff than the distal section of the catheter and thus the same is true for the mandrel.

Whereas with the prior art metal mandrel, grounding is one of the few means for tapering the diameter (i.e., having a diameter that gets smaller as the length of the mandrel is traversed from the proximal end to the distal end) and achieving a varying stiffness (the larger the diameter the more stiff the mandrel), non-metal mandrels may have dimensional and morphological changes achieved in a variety of ways. For example, the diameter of a non-metal mandrel maybe tapered from the proximal end to the distal end, by a taper extruding, or by necking the mandrel at high temperatures during the initial fabrication of the mandrel. Sometimes, annealing the proximal portion of the mandrel induces a higher crystallinity which also makes the annealed proximal portion of the mandrel more stiff than the non-annealed distal portion of the mandrel.

By providing means for supporting a catheter shaft such that the stiffness of the support maybe varied as needed, the non-metal mandrel of the present invention also eliminates the previous limitation requiring the catheter shaft to be made of a stiff polymer in order to provide the desired pushability. Further, the non-metal mandrel of the present invention is fabricated from a material that is more compatible with the standard materials used for the catheter shaft. This compatibility between the mandrel and the catheter shaft allows the mandrel to be able to be fused to the shaft by heating if desired. The fusion process locks the mandrel in place and makes the external force and support to be applied more efficiently.

Thus, the non-metal mandrel of the present invention provides numerous advantages over the prior art metal mandrel. The non-metal mandrel allows for both dimensional and morphological changes that may be varied to control the stiffness characteristics of both the mandrel and the catheter shaft or sheath the mandrel is inserted into. The capability of varying the stiffness of the mandrel along its length allows the mandrel to provide the greater desired pushability without sacrificing the needed flexibility in the distal shaft. This also reduces the need for stiff polymer catheter shafts, which greatly reduces the chance of kinking along the catheter shaft.

CLAIMS

What is claimed:

1. An apparatus comprising:

a rod comprised of a non-metal, said rod adapted to reinforce a hollow tube.

2. The apparatus of claim 1 wherein said material is selected from the group consisting of: polyamides, PEEK, PPS, PEI, PI, liquid crystalline polymers, glass reinforced polymers, graphite reinforced polymers, and any combination thereof.

3. The apparatus of claim 1 wherein said rod has a proximal section and a distal section and said proximal section has a larger diameter than said distal section.

4. The apparatus of claim 3 wherein said distal section is more flexible than said proximal section.

5. The apparatus of claim 1, said rod having a proximal section and a distal section wherein said proximal section is annealed to induce a higher crystallinity such that said proximal section is stiffer than said distal section.

6. A catheter comprising:

an outer member;

a hollow inner member extending through said outer member;

an outer lumen between said inner and outer members; and,

a rod comprising a non-metal, said rod extending through said outer lumen.

7. The apparatus of claim 6 wherein said material is selected from the group consisting of: polyamides, PEEK, PPS, PEI, PI, liquid crystalline polymers, reinforced polymers, glass reinforced polymers, graphite reinforced polymers, and any combination thereof.

8. The catheter of claim 6 wherein said rod has a proximal section and a distal section and said proximal section has a larger diameter than said distal section.

9. The catheter of claim 8 wherein said distal section is more flexible than said proximal section.

10. The catheter of claim 6, said rod having a proximal section and a distal section, wherein said proximal section is annealed to induce a higher crystallinity such that said proximal section is stiffer than said distal section.

ABSTRACT OF THE INVENTION

An apparatus for providing support along the length of a catheter is described. The present invention consists of a mandrel fabricated from a non-metal. The mandrel extends through the lumen of a dilatation catheter to provide added support and stiffness to the catheter shaft. The stiffness along the length of the non-metal mandrel may easily be varied by making dimensional or morphological changes to the polymeric mandrel.

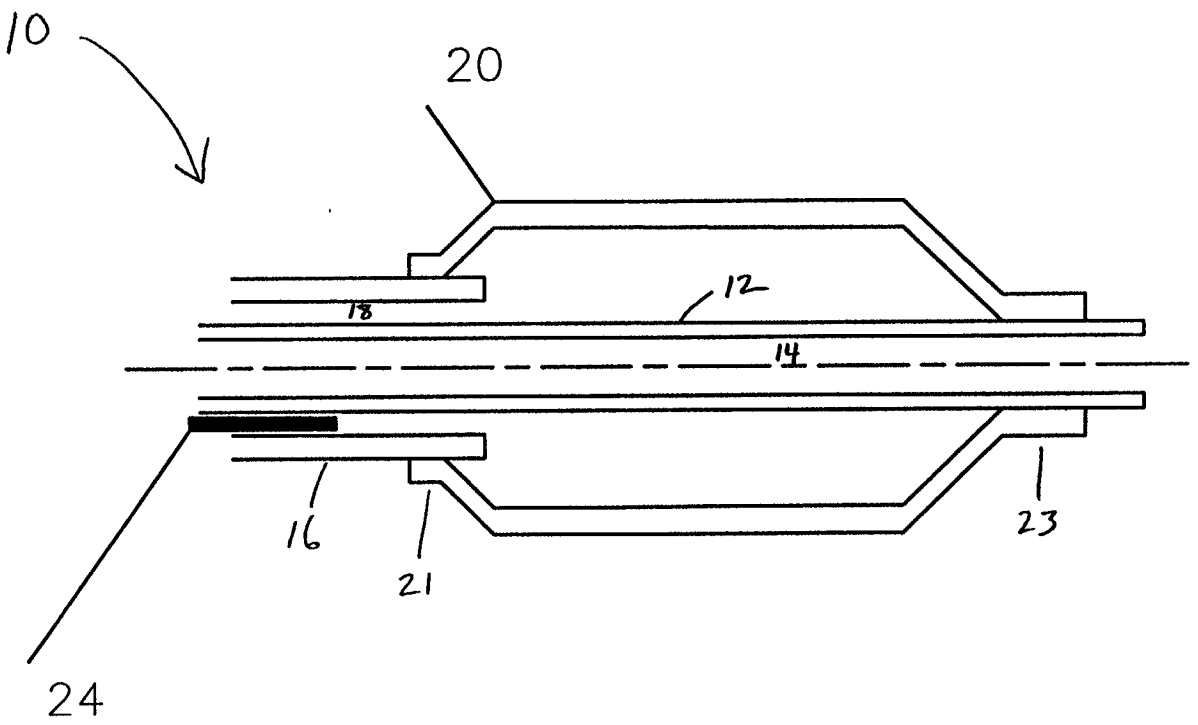

FIG. 1A

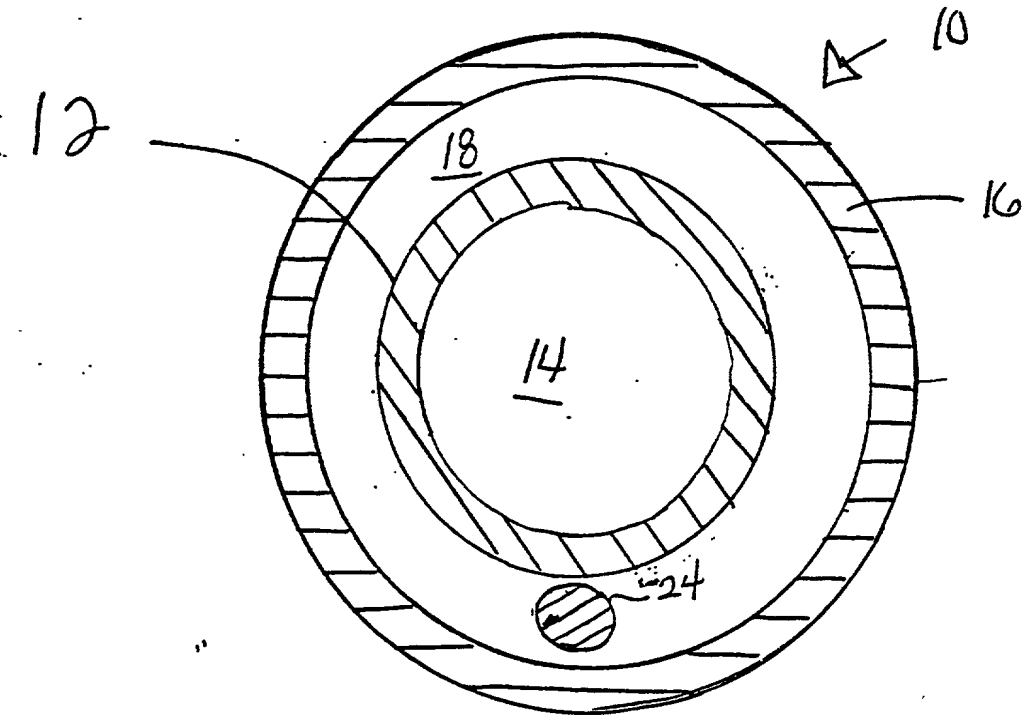

Figure 1B Section A-A

Attorney's Docket No.: 003764.P006 PATENT

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION
(FOR GUIDANT CORPORATION PATENT APPLICATIONS)

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below, next to my name.

I believe I am the original, first, and sole inventor (if only one name is listed below) or an original, first, and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

NON-METAL REINFORCING MANDREL

the specification of which

X is attached hereto.
___ was filed on_____ as
United States Application Number_____
or PCT International Application Number_____
and was amended on _____.
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claim(s), as amended by any amendment referred to above.

I do not know and do not believe that the claimed invention was ever known or used in the United States of America before my invention thereof, or patented or described in any printed publication in any country before my invention thereof or more than one year prior to this application, that the same was not in public use or on sale in the United States of America more than one year prior to this application, and that the invention has not been patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on an application filed by me or my legal representatives or assigns more than twelve months (for a utility patent application) or six months (for a design patent application) prior to this application.

I acknowledge the duty to disclose all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)			Priority Claimed	
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No

I hereby claim the benefit under title 35, United States Code, Section 119(e) of any United States provisional application(s) listed below

(Application Number)	Filing Date
(Application Number)	Filing Date

I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s), or 365(c) of any PCT International application designating the United states of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I acknowledge the duty to disclose all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

(U.S. Parent Application or) PCT Parent No.)	Parent Filing Date	(Status -- patented, pending, abandoned)	Parent Patent No. (if applicable)
(U.S. Parent Application or) PCT Parent No.)	Parent Filing Date	(Status -- patented, pending, abandoned)	Parent Patent No. (if applicable)

I hereby appoint the persons listed on Appendix A hereto (which is incorporated by reference and a part of this document) as my respective patent attorneys and patent agents, with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith.

Send correspondence to Andrew C. Chen, BLAKELY, SOKOLOFF, TAYLOR &
(Name of Attorney or Agent)
ZAFMAN LLP, 12400 Wilshire Boulevard, 7th Floor, Los Angeles, California 90025 and direct telephone calls to Andrew C. Chen, (408) 720-8300.
(Name of Attorney or Agent)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of Sole/First Inventor Jeong S. Lee

Inventor's Signature _____ Date _____

Residence Diamond Bar, California Citizenship Republic of Korea
(City, State) (Country)

Post Office Address 23637 E. Goldrush Drive
Diamond Bar, California 91765

Full Name of Second/Joint Inventor Ken Wantink

Inventor's Signature _____ Date _____

Residence _____ Citizenship _____
(City, State) (Country)

Post Office Address _____

Full Name of Third/Joint Inventor _____

Inventor's Signature _____ Date _____

Residence _____ Citizenship _____
(City, State) (Country)

Post Office Address _____

Full Name of Fourth/Joint Inventor _____

Inventor's Signature _____ Date _____

Residence _____ Citizenship _____
(City, State) (Country)

Post Office Address _____

APPENDIX A

William E. Alford, Reg. No. 37,764; Farzad E. Amini, Reg. No. P42,261; Aloysius T. C. AuYeung, Reg. No. 35,432; William Thomas Babbitt, Reg. No. 39,591; Carol F. Barry, Reg. No. 41,600; Jordan Michael Becker, Reg. No. 39,602; Bradley J. Bereznak, Reg. No. 33,474; Michael A. Bernadicou, Reg. No. 35,934; Roger W. Blakely, Jr., Reg. No. 25,831; Gregory D. Caldwell, Reg. No. 39,926; Ronald C. Card, Reg. No. P44,587; Thomas M. Coester, Reg. No. 39,637; Stephen M. De Klerk, under 37 C.F.R. § 10.9(b); Michael Anthony DeSanctis, Reg. No. 39,957; Daniel M. De Vos, Reg. No. 37,813; Robert Andrew Diehl, Reg. No. 40,992; Matthew C. Fagan, Reg. No. 37,542; Tarek N. Fahmi, Reg. No. 41,402; James Y. Go, Reg. No. 40,621; James A. Henry, Reg. No. 41,064; Willmore F. Holbrow III, Reg. No. P41,845; Sheryl Sue Holloway, Reg. No. 37,850; George W Hoover II, Reg. No. 32,992; Eric S. Hyman, Reg. No. 30,139; Dag H. Johansen, Reg. No. 36,172; William W. Kidd, Reg. No. 31,772; Erica W. Kuo, Reg. No. 42,775; Michael J. Mallie, Reg. No. 36,591; Andre L. Marais, under 37 C.F.R. § 10.9(b); Paul A. Mendonsa, Reg. No. 42,879; Darren J. Milliken, Reg. 42,004; Lisa A. Norris, Reg. No. P44,976; Chun M. Ng, Reg. No. 36,878; Thien T. Nguyen, Reg. No. 43,835; Thinh V. Nguyen, Reg. No. 42,034; Dennis A. Nicholls, Reg. No. 42,036; Kimberley G. Nobles, Reg. No. 38,255; Daniel E. Ovanezian, Reg. No. 41,236; Babak Redjaian, Reg. No. 42,096; William F. Ryann, Reg. 44,313; James H. Salter, Reg. No. 35,668; William W. Schaal, Reg. No. 39,018; James C. Scheller, Reg. No. 31,195; Jeffrey Sam Smith, Reg. No. 39,377; Maria McCormack Sobrino, Reg. No. 31,639; Stanley W. Sokoloff, Reg. No. 25,128; Judith A. Szepesi, Reg. No. 39,393; Vincent P. Tassinari, Reg. No. 42,179; Edwin H. Taylor, Reg. No. 25,129; John F. Travis, Reg. No. 43,203; George G. C. Tseng, Reg. No. 41,355; Joseph A. Twarowski, Reg. No. 42,191; Lester J. Vincent, Reg. No. 31,460; Glenn E. Von Tersch, Reg. No. 41,364; John Patrick Ward, Reg. No. 40,216; Charles T. J. Weigell, Reg. No. 43,398; Kirk D. Williams, Reg. No. 42,229; James M. Wu, Reg. No. P45,241; Steven D. Yates, Reg. No. 42,242; Ben J. Yorks, Reg. No. 33,609; and Norman Zafman, Reg. No. 26,250; my patent attorneys, and Andrew C. Chen, Reg. No. 43,544; Justin M. Dillon, Reg. No. 42,486; Paramita Ghosh, Reg. No. 42,806; and Sang Hui Kim, Reg. No. 40,450; my patent agents, of BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP, with offices located at 12400 Wilshire Boulevard, 7th Floor, Los Angeles, California 90025, telephone (310) 207-3800, and James R. Thein, Reg. No. 31,710, my patent attorney.

I also hereby appoint Earl A. Bright II, Reg. No. 37,045; Thomas A. Hassing, Reg. No. 36,159; Tim L. Kitchen, Reg. No. 41,900; Philip S. Yip, Reg. No. 37,265; my attorneys; of Guidant Corporation located at 3200 Lakeside Drive, Santa Clara, CA 95054, telephone (408) 845-3000, with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith.

APPENDIX B

Title 37, Code of Federal Regulations, Section 1.56
Duty to Disclose Information Material to Patentability

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclosure information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclosure all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) Prior art cited in search reports of a foreign patent office in a counterpart application, and

(2) The closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made or record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application;

(2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.